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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,394	11/14/2003	Carsten Sjoholm	10094.210-US	9916

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	**PAPER NUMBER**
1656	
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08/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,394	SJOEHOLM ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/779,323.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *filed11/03 & 4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 13-26 are under examination on the merits. Claims 1-12 are canceled.

Specification

The specification is objected for the following reasons:

(1) The priority data in the first page of the specification needs updating.

(2) Hyperlink language (see e.g. pages 3 and 10 of the specification) must be avoided everywhere in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-19, 22-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Said claims are directed a **genera** of methods utilizing proteases, which have been inadequately described in the specification.

The specification fails to teach which specific amino acids in claimed proteases are in charge of rendering said products acid-resistant proteases. Current state of prior art teaches that many SEQID NO:1 homologs (of 70% or higher identity) are not necessarily proteases, let alone acid –resistant proteases. Therefore, some additional

structural information about the critical residues in claimed acid resistant protease homologs is necessary such that they could be distinguished from all other enzymes specially non-acid resistant proteases. Such information is currently lacking in the specification. All applicant provides is a **single species** (namely SEQ ID NO:1) which is insufficient to put the skilled artisan in possession of all members of the genera as broadly claimed. Since SEQ ID NO:1 homologs are inadequately described methods of use thereof are also inadequately described.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-19 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bedford et. Al. (WO 96/05739, Feb 1996, cited in the IDS) in view of Snow-Brand-Milk-Prod. patent (JP 02255081, 1990, see abstract in English, cited in the IDS), from now on referred to as Snow-Brand. Bedford teaches methods of preparation of an animal feed (such as cereals containing vegetable proteins) comprising adding an

enzyme feed additive in the diet of an animal, wherein said feed additive comprises a xylanase, a protease and a beta-glucanase (see abstract and pages 19-22). Bedford uses Bacillus amyloliquefaciens as a source of its protease and does not teach a protease from Nocardiopsis sp. as a source of its protease.

Snow-Brand's patent teaches a thermostable alkaline protease from Nocardiopsis sp. which has a pH optimum of 10-12, a temperature optimum of 60-70°C, has a molecular weight of 21 Kilodalton and maintains residual activity of above 80% at pH 4-8. Since the enzyme source of Snow-Brand's patent is identical to the protease of this invention and pH/temperature-activity profile and molecular weight of Snow-Brand's protease is almost identical to SEQ ID NO:1 of this invention it is reasonable to assume that, its protease is at least 70% identical to SEQ ID NO:1 of this invention, even though Snow-Brand does not explicitly discloses an amino acid composition for its enzyme

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to start with the method of animal feed preparation of Bedford and replace its protease which is mainly stable and active at alkaline pH's with that from Snow-Brand's patent. One of ordinary skill in the art is motivated to replace the protease of Bedfrod with that from the Snow-Brand patent because Snow-Brand's protease retains high levels of residual activity at acidic pH's and can act on the feed in animal stomach (acidic environment) longer than the Bacillus protease in order to

release more energy. Obviously, such protease replacement will improve the nutritional value of the feed, and rendering it more economical.

One of ordinary skill has a reasonable expectation of success in preparing feed comprising the protease including those from Nocardoposis sp. because methods of preparing animal feed comprising various proteins and protease are well established in the prior art.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 20-21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 4-5 of prior U.S. Patent No. 6,855,548. This is a double patenting rejections there in no scope differences between instant claims 20-21 and claims 4-5 of said U.S. patent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-19, 22-26 are rejected on the ground of nonstatutory double patenting over claims 1-3 and 6 of U. S. Patent No. 6,855,548 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 13-19 of this invention embrace the scope of claims 1-3 of said Patent. Likewise, instant claims 22-26 embrace the scope of claim 6 in said U.S. Patent.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 13-18, 22-25 are rejected on the ground of nonstatutory double patenting over claims 18-19 and 6 of U. S. Patent No. 7,179,630 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Claims 19 of said patent embraces the scope of claims 13-18 of this invention. Likewise, instant claim 18 of said patent embraces the scope of claims 22-25 in this application.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 13-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/544,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claim 18 of said application embraces the scope of instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M Monshi

Maryam Monshipouri Ph.D.

Primary Examiner